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Abstract

A systematic review of prescription pattern monitoring studies and their effectiveness in promoting rational use of medicines

Prescription pattern monitoring studies (PPMS) are a tool for assessing the prescribing, dispensing and distribution of medicines. The main aim of PPMS is to facilitate rational use of medicines (RUM). There is paucity of published data analysing the effectiveness of PPMS. The present review has been done to assess the effectiveness of prescription pattern monitoring studies in promoting RUM. Data search was conducted on internet. A multitude of PPMS done on different classes of drugs were collected and analyzed. PPMS using WHO prescribing indicators were also included. The present article reviews various prescription pattern monitoring studies of drugs conducted all over country and abroad. It was observed in the majority of such studies that physicians do not adhere to the guidelines made by regulatory agencies leading to irrational use of medicines. This in turn leads to increased incidence of treatment failure, antimicrobial resistance and economic burden on the patient and the community as a whole. The treatment of diseases by the use of essential drugs, prescribed by their generic names, has been emphasized by the WHO and the National Health Policy of India. We conclude that the prescription monitoring studies provide a bridge between areas like rational use of drugs, pharmacovigilance, evidence based medicine, pharmacoconomics, pharmacogenetics and ecopharmacovigilance. In India, this is the need of the hour to utilise the data generated by so many prescription pattern monitoring studies done in every state and on every drug, so that the main aim of promoting rational use of drugs is fulfilled.

Key words: Drug auditing, drug utilization pattern, pharmacoepidemiology, prescription-monitoring, rational use of drugs

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INTRODUCTION

Medicines are an integral part of the health care, and modern health care is impossible without the availability of necessary medicines. They not only save lives and promote health, but prevent epidemics and diseases too. Accessibility to medicines is the fundamental right of every person.^[1]

However, to bring optimal benefit, they should be safe, efficacious, cost-effective and rational.

Drug utilization research was defined by World Health Organization (WHO) in 1977 as a marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social and economic consequences. Pharmacoepidemiology is the study of the use and effects/side-effects of drugs in large numbers of people with the purpose of supporting the rational and cost-effective use of drugs in the population thereby improving health outcomes. Drug utilization research is thus an essential part of pharmacoepidemiology as it describes the extent, nature and determinants of drug exposure. Over time, the distinction between these two terms has become less sharp, and they are sometimes used interchangeably. Together, drug utilization research and pharmacoepidemiology may provide insights into many aspects of drug use and drug-prescribing. They provide much useful information on indirect data on morbidity, treatment cost of illness, therapeutic compliance, incidence of adverse reactions, effectiveness of drug consumption and choice of comparators.^[2]

Prescription pattern monitoring studies (PPMS) are drug utilization studies with the main focus on prescribing, dispensing and administering of drugs. They promote appropriate use of monitored drugs and reduction of abuse or misuse of monitored drugs. PPMS also guide and support prescribers, dispensers and the general public on appropriate use of drugs, collaborate and develop working relationship with other key organizations to achieve a rational use of drugs. Prescription Patterns explain the extent and profile of drug use, trends, quality of drugs, and compliance with regional, state or national guidelines like standard treatment guidelines, usage of drugs from essential medicine list and use of generic drugs. There is increasing importance of PPMS because of a boost in marketing of new drugs, variations in pattern of prescribing and consumption of drugs, growing concern about delayed adverse effects, cost of drugs and volume of prescription.^[3]

The aim of PPMS is to facilitate the rational use of drugs in a population. Irrational use of medicines is a major problem worldwide. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards. The rational use of medicines (RUM) is defined as “Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.”^[2]

A large number of studies have been conducted to study the prescribing pattern of physicians across the country. The studies conclude the irrational prescribing practices of prescribers and suggest RUM at all levels of health care delivery system. However, no systematic reviews, meta-analyses, or randomized controlled trials are present about the relevance of PPMS in promoting rational use of drugs. The present review has been done to assess the effectiveness of PPMS in developing RUM. This study was conducted with the aim of analyzing the prescribing practices of physicians and to assess the extent to which the goal of RUM has been achieved. The drugs frequently prescribed by the physicians for disease conditions like diabetes, schizophrenia, hypertension, epilepsy, inflammatory conditions such as osteoarthritis have been included in this study. An effort has been made to also include the prescribing trends of antimicrobials due to the growing concern of antimicrobial resistance. Data search pertaining to assessment of PPMS was conducted on the internet. A plethora of information on the prescribing trends of physicians was available which has been summarized in this study.

PRESCRIPTION PATTERN MONITORING STUDIES IN INDIA

Prescription pattern monitoring of antidiabetic drugs

A prospective, cross-sectional study was carried out in medicine outpatient clinic of tertiary care hospital, Ahmedabad for 8 weeks. Patients with type-2 diabetes and on drug therapy for at least 1-month were included.^[4] A similar study was undertaken to identify patterns of antidiabetic drugs prescribing in patients with established type 2 diabetes mellitus (T2DM) who attended the endocrinology Outpatient Clinic in Postgraduate Institute of Medical Education and Research, Chandigarh, India.^[5] A prospective observational study was carried out for a period of 5 months in diabetic patients who visited the medicine outdoor department of a tertiary care teaching hospital in India to assess prescription pattern, cost of antidiabetic drugs and adherence to treatment guidelines.^[6] All of these studies demonstrated that prescription pattern of antidiabetic drugs adhere to standard treatment guidelines.

Prescription pattern monitoring of antipsychotic drugs

The study was conducted in outpatients of the Department of Psychiatry, Chhatrapati Shahuji Maharaj Medical University, U.P., Lucknow.^[7] Another study was conducted in which an audit of the prescription pattern of antipsychotic drugs in patients with schizophrenia, in a tertiary care center in India was performed.^[8] A similar study was done in psychiatry outpatient clinic of a tertiary care hospital in India.^[9] These studies concluded that the poly-pharmacy of antipsychotic drugs is common.

Prescription pattern monitoring of antiasthmatic drugs

A prescription-monitoring study was conducted to evaluate the drug-prescribing trend of antiasthmatic drugs in urban and rural areas of Saurashtra region, Gujarat.^[10] Another drug utilization or prescription-monitoring study was conducted in various hospitals of Shamli, Prabuddha Nagar, Uttar Pradesh, India. The study was conducted in three famous hospitals of Shamli on 330 patients.^[11] A similar prescription-monitoring study was conducted to establish the drug-prescribing trend of antiasthmatic drugs in various hospitals of Gorakhpur.^[12] It is concluded that the prescribing pattern of antiasthmatics does not completely meet standard treatment guidelines.

Prescription pattern monitoring of antihypertensive drugs

A prescription based survey among patients with established hypertension was conducted at the Medicine Outpatient Department (OPD) of University Teaching Hospital in South Delhi, India. It was a prospective study aimed to investigate the use of antihypertensive drugs and to identify whether such pattern of prescription is appropriate in accordance with international guidelines for the management of hypertension.^[13] A similar prospective observational study was carried out for a period of 6 months (January 2011–June 2011) in an OPD of Rohini Superspeciality Hospital, Warangal, Andhra Pradesh to assess the prescribing pattern for antihypertensives in geriatric patients.^[14] Another cross-sectional study was carried out to evaluate the prescribing pattern of antihypertensive in T2DM patients and compare with existing recent guidelines in North India.^[15] The above mentioned studies revealed that the antihypertensive utilization pattern is in accordance with the international guidelines for treatment of hypertension. There is considerable use of different antihypertensive drug combinations for the treatment of hypertension and such practice has a positive impact on the overall blood pressure control.

Prescription pattern monitoring of antiepileptic drugs

A prospective study was carried out between January and April 2011 in the Neurosciences Centre OPD at All India Institute of Medical Sciences, New Delhi to analyze prescription pattern and utilization behavior of antiepileptic drugs as well as analysis of quality of life data.^[16] Another study was carried out in Cuttack to get an insight into the type of epileptic seizures and to assess the drug utilization pattern of antiepileptic drugs.^[17] Another study conducted in India evaluated the utilization pattern of antiepileptic drugs in different hospitals.^[18] All these studies concluded that the poly-pharmacy is commonly observed in prescribing antiepileptic drugs and is the cause of concern.

Prescription pattern monitoring of nonsteroidal antiinflammatory drugs

Nonsteroidal antiinflammatory drugs (NSAIDs) constitute one of the largest group of pharmaceutical agents used all over the world. They are also the most common drugs reported causing adverse drug reactions by drug regulatory agencies. Several studies have been conducted to study the prescription pattern of NSAIDs. A drug utilization study was conducted in the out-patient clinic of the orthopedics department from December 2002 to June 2003 in a tertiary care hospital in India to determine the quality of prescribing.^[19] Another prospective study was conducted in Orthopedics OPD of a tertiary care teaching hospital in Dehradun to analyze the prescribing pattern of NSAIDs.^[20] These studies suggest that the prescribing pattern of NSAIDs was not in accordance with current guidelines mentioned by regulatory agencies. Moreover, the adverse effect profile should be considered while prescribing these drugs.

Prescription pattern monitoring of antibiotics

Monitoring the antibiotic utilization pattern is of growing concern due to increase in antibiotic resistance, lack of adherence to standard treatment guidelines and rise in health care expenditure. Various studies have been conducted to assess the prescribing practices of medical practitioners in this context. A cross-sectional prospective study was carried out in six inpatient department (Surgery, Orthopedics, ENT, Ophthalmology, Medicine and Pediatrics) of a 550-bedded tertiary care hospital in Trivandrum to evaluate the prescribing pattern of antibiotics.^[21] A similar study was conducted to analyze the current usage of antimicrobial agents in the Medical Intensive Care Unit of a teaching hospital in Central India.^[22] Another study was done to assess the antibiotics usage in the pediatric population.^[23] The survey was conducted at the outpatient facilities in the South 24 Parganas district of West Bengal. Data were collected prospectively by interviewing patients immediately after patient-physician and patient-dispenser encounters. A total of 312 prescriptions were analyzed.^[24] A cross-sectional study was carried out to analyze and compare antibiotic prescribing for inpatients, in two private sector tertiary care hospitals; one teaching and one nonteaching in Ujjain.^[25] All these studies concluded inappropriate use of antibiotics and lack of adherence to standard treatment guidelines resulting in increased incidence of antibiotic resistance.

How effective prescription pattern monitoring studies are in India?

A large number of PPMS have been done all over the world to determine the quality of prescribing practices of physicians and promote RUM. However, it has been observed in the majority of such studies that physicians

do not adhere to the guidelines made by regulatory agencies leading to irrational use of medicines. This in turn leads to increase the incidence of treatment failure, antimicrobial resistance and economic burden on the patient and the community as a whole. The treatment of diseases by the use of essential drugs, prescribed by their generic names, has been emphasized by the WHO and the National Health Policy of India.^[26] Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.^[1] The National List of Essential Medicines of India (NLEMI 2011) was revised recently by the Ministry of Health and Family Welfare, Government of India, in June 2011, nearly 8 years after the previous list, on the directions of the Supreme Court of India.^[27] The list was accessed from the official website of the drug regulatory authority of India, the Central Drugs Standard Control Organization,^[28] downloaded and reviewed by comparing it with the 17th Model WHO EML, March 2011, the 3rd WHO Model EML for children, March 2011 and the National EML 2003.^[29]

In United States, drug utilization studies are primarily developed in the form of prescription drug monitoring program (PDMP) at institutional, state and national level. A PDMP is a tool that can be used to address prescription drug diversion and abuse. PDMPs serve multiple functions, including: Patient care tool; drug epidemic early warning system; and drug diversion and insurance fraud investigative tool. They help prescribers avoid drug interactions and identify drug-seeking behaviors or “doctor shopping.”^[30] In European countries, drug utilization research also describe and compare the patterns of specific groups of drugs.^[31] In developing the country such as India, PPMS are done at individual level and not as a national program in contrast to developed countries. Hence, the data generated is not analyzed and used in promoting RUM.

A large number of socioeconomic factors affect drug utilization in India. Like; illiteracy, poverty, multiple health care systems, drug advertisement and promotions, sales without prescription, over the counter drugs etc.^[32] Cost factors like prices of drug, entry of new drug in market, volume of drug use; Population factors like changes in total population, demographics, change in health status of a population; system factors like changes in health program and health system reforms and restructuring, shift of drug provision from hospital to community, changes in policies

and program; research and technology related factors include new treatment approaches, drugs replacing surgery, availability of more diagnostic technologies, evidence-based curative approaches, use of newer pharmaceutical technology; practice and people related factors like changes in prescribing and dispensing, number and mix of prescribers, multiple doctoring, consumer expectations and behavior and wastage; pharmaceutical industry related factors like new drug products, promotion of drugs to physicians, drug sampling and consumer advertising. These factors present important challenges in developing the country such as India for development of indicators to monitor trends and results that affect the performance of health care system and health of the population.^[33]

It is very important that the PPMS should be consultative and transparent, selection criteria be explicit, selection of the medicines be linked to evidence-based standard clinical guidelines, clinical guidelines and the list be divided into levels of care, and are regularly reviewed and updated. The effectiveness of PPMSs can be conceptualized in terms of their impact in ensuring the appropriate use of prescription controlled substances, reducing their diversion and abuse, and improving health outcomes, both at the patient and community levels. This impact is maximized when prescription history data are, to the extent technologically feasible, complete and accurate; analyzed appropriately and expeditiously; made available in a proactive and timely manner; disseminated in ways and formats that best serve the purposes of end users; and applied in all relevant domains by all appropriate users. This suggests that PPMSs can be thought of as information systems with inputs, internal operations, outputs, and customers who make use of their products.^[34]

CONCLUSION

The PPMS are an ever evolving field. It compares observed patterns of drug use and current recommendations and guidelines. This study concludes the ineffectiveness of PPMS in developing RUM in India, and stringent measures should be taken to rectify it. Feedback should be provided to prescribers on the basis of data collected. How many prescribers actually utilize the data in clinical practice is questionable. The aim of PPMS is to produce rational prescribers rather than confused practitioners in the therapeutic jungle. Unless strict rules are formed by the regulatory authorities, it is difficult to modify or bring changes in the system. PPMS provide a bridge between areas like RUM, pharmacovigilance, evidence-based medicine, Pharmacoeconomics, Pharmacogenetics and Ecopharmacovigilance. In India, this is the need of the hour to utilize the data generated by so many PPMSs done

in every state and on every drug so that the main aim of promoting rational use of drugs is fulfilled.

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